

I. Amendments

The claims have been amended as set forth above in order to expedite the prosecution of this case. Claims 6, 9, 10, 12, 21-26 have been rewritten in independent form to include all of the limitations of the base claim and any intervening claims. Likewise, new claims 34-39, correspond to original claims 21-26, respectively, rewritten in independent form to include all of the limitations of the base claims and any intervening claims. Support for the new claims may be found in original claim 21-26.

Claims 12 and 19 have been amended to accurately number the method components.

No new matter has been added by these amendments.

Also attached is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **“Version with Markings to Show Changes Made.”**

II. Rejection Under 35 U.S.C. §112, second paragraph

Claims 2, 12 and 19 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 2 has been cancelled; claim 12 has been rewritten in independent format and claim 19 has been amended to accurately number the method components, thus obviating the rejection.

Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112, second paragraph.

III. Rejection under 35 U.S.C. §102(b)

Claims 1-5, 7-8, 11, 13-17 and 27-30 were rejected under 35 U.S.C. §102(b) as being anticipated by Goldstein *et al.* (U.S. Pat. No. 5,527,690).

Claims 1-5, 7-8, 11, 13-17 and 27-30 have been cancelled, thus obviating the rejection.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35

U.S.C. §102(b).

IV. Claim Objections

Claims 6, 9, 10 and 21-26 have been objected to as being dependent upon a rejected base claim. The Examiner has stated that these claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

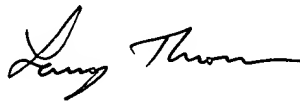
Applicants have amended these claims accordingly, and respectfully request withdrawal of the objection.

V. Conclusion

In view of the above remarks, the applicants submit that the claims now pending are in condition for allowance. A Notice of Allowance is, therefore, respectfully requested.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4405.

Respectfully submitted,



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**Version with Markings to Show Changes Made**

**In the Claims:**

Claims 1-5, 7-8, 11, 13-17 and 27-30 have been cancelled, claims 34-38 have been added, and claims 6, 9, 10, 12, 19, 21 and 23-26 have been amended as follows:

6. (Amended) ~~The molecular switch according to claim 2, wherein said second promoter is a regulatable promoter.~~

A molecular switch, comprising:  
a first nucleic acid construct having  
(i) a DNA response element for a transcriptional regulatory protein operably linked to a first promoter;  
(ii) a non-native compound binding sequence which is the same as, overlapping, or adjacent to said DNA response element for binding to a DNA binding compound;  
(iii) a transgene under the control of said first promoter;  
(iv) a second nucleic acid construct having the coding sequence for a transcriptional regulatory protein operably linked to a regulatable promoter, and the DNA binding compound.

9. (Amended) ~~The molecular switch according to claim 1, wherein said first nucleic acid construct is an adenovirus vector.~~

A molecular switch, comprising:  
an adenovirus vector having  
(i) a DNA response element for a transcriptional regulatory protein operably linked to a first promoter;  
(ii) a non-native compound binding sequence which is the same as, overlapping, or adjacent to said DNA response element for binding to a DNA binding compound;  
(iii) a transgene under the control of said first promoter; and  
the DNA binding compound.

10. (Amended) ~~The molecular switch according to claim 1, wherein said first~~

~~nucleic acid construct is an adeno-associated virus vector.~~

A molecular switch, comprising:  
an adeno-associated virus vector having  
(i) a DNA response element for a transcriptional regulatory protein operably linked  
to a first promoter;  
(ii) a non-native compound binding sequence which is the same as, overlapping,  
or adjacent to said DNA response element for binding to a DNA binding compound;  
(iii) a transgene under the control of said first promoter; and  
the DNA binding compound.

12. (Amended) ~~The molecular switch according to claim 11, further comprising:~~  
A molecular switch, comprising:  
a first nucleic acid construct having  
(i) a DNA response element for a transcriptional regulatory protein operably linked  
to a regulatable promoter;  
(ii) a non-native compound binding sequence which is the same as, overlapping,  
or adjacent to said transcriptional regulatory protein DNA response element for binding to  
a DNA binding compound;  
(iii) a transgene and the coding sequence for a transcriptional regulatory protein  
under the control of and operably linked to said regulatable promoter;  
~~(iv)~~ (iv) the coding sequence for a transcriptional regulatory protein operably linked  
to said regulatable promoter; and  
the DNA binding compound.

19. (Amended) The method according to claim 18, comprising:  
~~(iv)~~ (iii) further transforming said cell with a second nucleic acid construct having a  
nucleic acid sequence encoding a transcriptional regulatory protein operably linked to a  
second promoter.

21. (Amended) ~~The molecular switch according to claim 1 or 11,~~

A molecular switch, comprising:  
a first nucleic acid construct having  
(i) a DNA response element for a transcriptional regulatory protein operably linked  
to a first promoter;  
(ii) a non-native compound binding sequence which is the same as, overlapping,  
or adjacent to said DNA response element for binding to a DNA binding compound;  
(iii) a transgene under the control of said first promoter; and  
the DNA binding compound,

wherein said transcriptional regulatory protein has a DNA binding sequence selected from the group consisting of a UL9 sequence, an NF- $\kappa$ B sequence, a GAL4 sequence, a ZFHD1 sequence, a LacR sequence, a TetR sequence, a LexA sequence, and the ecdysone receptor binding sequence.

22. (Amended) ~~The cell according to claim 16,~~  
A cell comprising a molecular switch comprising  
a first nucleic acid construct having  
(i) a DNA response element for a transcriptional regulatory protein operably linked  
to a first promoter;  
(ii) a non-native compound binding sequence which is the same as, overlapping,  
or adjacent to said DNA response element for binding to a DNA binding compound;  
(iii) a transgene under the control of said first promoter; and  
the DNA binding compound,

wherein the DNA binding sequence of said transcriptional regulatory protein is selected from the group consisting of a UL9 sequence, an NF- $\kappa$ B sequence, a GAL4 sequence, a ZFHD1 sequence, a LacR sequence, a TetR sequence, a LexA sequence, and the ecdysone receptor binding sequence.

23. (Twice Amended) ~~The molecular switch according to claim 1 or 11,~~  
A molecular switch, comprising:  
a first nucleic acid construct having

(i) a DNA response element for a transcriptional regulatory protein operably linked to a first promoter;

(ii) a non-native compound binding sequence which is the same as, overlapping, or adjacent to said DNA response element for binding to a DNA binding compound;

(iii) a transgene under the control of said first promoter; and  
the DNA binding compound,

wherein said DNA response element binds a transcriptional regulatory protein which comprises an activator domain selected from the group consisting of VP16, NF- $\kappa$ B, Gal4, TFE3, ITF1, Oct-1, Sp1, Oct-2, NFY-A, ITF2, c-myc, and CTF.

24. (Twice Amended) ~~The cell according to claim 16,~~ A cell comprising a molecular switch comprising  
a first nucleic acid construct having

(i) a DNA response element for a transcriptional regulatory protein operably linked to a first promoter;

(ii) a non-native compound binding sequence which is the same as, overlapping, or adjacent to said DNA response element for binding to a DNA binding compound;

(iii) a transgene under the control of said first promoter; and  
the DNA binding compound,

wherein the DNA response element binds a transcriptional regulatory protein which comprises an activator selected from the group consisting of VP16, NF- $\kappa$ B, Gal4, TFE3, ITF1, Oct-1, Sp1, Oct-2, NFY-A, ITF2, c-myc, and CTF.

25. (Twice Amended) ~~The molecular switch according to claim 1 or 14~~  
A molecular switch, comprising:  
a first nucleic acid construct having

(i) a DNA response element for a transcriptional regulatory protein operably linked to a first promoter;

(ii) a non-native compound binding sequence which is the same as, overlapping, or adjacent to said DNA response element for binding to a DNA binding compound;

(iii) a transgene under the control of said first promoter; and  
the DNA binding compound,

wherein the DNA response element binds a transcriptional regulatory protein which comprises a repressor selected from the group consisting of Kruppel (KRAB), kox-1, TetR, even-skipped, LacR, engrailed, hairy (HES), Groucho (TLE), RING1, SSB16, SSB24, Tup1, Nab1, AREB, E4BP4, HoxA7, EBNA3, Mad and v-erbA.

26. (Twice Amended) ~~The cell according to claim 16,~~  
A cell comprising a molecular switch comprising  
a first nucleic acid construct having  
(i) a DNA response element for a transcriptional regulatory protein operably linked  
to a first promoter;  
(ii) a non-native compound binding sequence which is the same as, overlapping,  
or adjacent to said DNA response element for binding to a DNA binding compound;  
(iii) a transgene under the control of said first promoter; and  
the DNA binding compound,

wherein the DNA response element binds a transcriptional regulatory protein which comprises a repressor selected from the group consisting of Kruppel (KRAB), kox-1, TetR, even-skipped, LacR, engrailed, hairy (hes), Groucho(TLE), RING1, SSB16, SSB24, Tup1, Nab1, AREB, E4BP4, HoxA7, EBNA3, Mad and v-erbA.

34. (New) A cell comprising a molecular switch comprising  
a first nucleic acid construct having  
(i) a DNA response element for a transcriptional regulatory protein operably linked  
to a regulatable promoter;  
(ii) a non-native compound binding sequence which is the same as, overlapping,  
or adjacent to said transcriptional regulatory protein DNA response element for binding to  
a DNA binding compound;  
(iii) a transgene and the coding sequence for a transcriptional regulatory protein  
under the control of and operably linked to said regulatable promoter; and

the DNA binding compound,  
wherein the DNA binding sequence of said transcriptional regulatory protein is selected from the group consisting of a UL9 sequence, an NF- $\kappa$ B sequence, a GAL4 sequence, a ZFHD1 sequence, a LacR sequence, a TetR sequence, a LexA sequence, and the ecdysone receptor binding sequence.

35. (New) A molecular switch, comprising:  
a first nucleic acid construct having  
(i) a DNA response element for a transcriptional regulatory protein operably linked to a regulatable promoter;  
(ii) a non-native compound binding sequence which is the same as, overlapping, or adjacent to said transcriptional regulatory protein DNA response element for binding to a DNA binding compound;  
(iii) a transgene and the coding sequence for a transcriptional regulatory protein under the control of and operably linked to said regulatable promoter; and  
the DNA binding compound,  
wherein said transcriptional regulatory protein has a DNA binding sequence selected from the group consisting of a UL9 sequence, an NF- $\kappa$ B sequence, a GAL4 sequence, a ZFHD1 sequence, a LacR sequence, a TetR sequence, a LexA sequence, and the ecdysone receptor binding sequence.

36. (New) A molecular switch, comprising:  
a first nucleic acid construct having  
(i) a DNA response element for a transcriptional regulatory protein operably linked to a regulatable promoter;  
(ii) a non-native compound binding sequence which is the same as, overlapping, or adjacent to said transcriptional regulatory protein DNA response element for binding to a DNA binding compound;  
(iii) a transgene and the coding sequence for a transcriptional regulatory protein under the control of and operably linked to said regulatable promoter; and



the DNA binding compound,

wherein said DNA response element binds a transcriptional regulatory protein which comprises an activator domain selected from the group consisting of VP16, NF- $\kappa$ B, Gal4, TFE3, ITF1, Oct-1, Sp1, Oct-2, NFY-A, ITF2, c-myc, and CTF.

37. (New) A cell comprising a molecular switch comprising a first nucleic acid construct having

(i) a DNA response element for a transcriptional regulatory protein operably linked to a regulatable promoter;

(ii) a non-native compound binding sequence which is the same as, overlapping, or adjacent to said transcriptional regulatory protein DNA response element for binding to a DNA binding compound;

(iii) a transgene and the coding sequence for a transcriptional regulatory protein under the control of and operably linked to said regulatable promoter; and the DNA binding compound,

wherein the DNA response element binds a transcriptional regulatory protein which comprises an activator selected from the group consisting of VP16, NF- $\kappa$ B, Gal4, TFE3, ITF1, Oct-1, Sp1, Oct-2, NFY-A, ITF2, c-myc, and CTF.

38. (New) A molecular switch, comprising: a first nucleic acid construct having

(i) a DNA response element for a transcriptional regulatory protein operably linked to a regulatable promoter;

(ii) a non-native compound binding sequence which is the same as, overlapping, or adjacent to said transcriptional regulatory protein DNA response element for binding to a DNA binding compound;

(iii) a transgene and the coding sequence for a transcriptional regulatory protein under the control of and operably linked to said regulatable promoter; and the DNA binding compound,

wherein the DNA response element binds a transcriptional regulatory protein

which comprises a repressor selected from the group consisting of Kruppel (KRAB), kox-1, TetR, even-skipped, LacR, engrailed, hairy (HES), Groucho (TLE), RING1, SSB16, SSB24, Tup1, Nab1, AREB, E4BP4, HoxA7, EBNA3, Mad and v-erbA.

39. (New) A cell comprising a molecular switch comprising  
a first nucleic acid construct having

(i) a DNA response element for a transcriptional regulatory protein operably linked  
to a regulatable promoter;

(ii) a non-native compound binding sequence which is the same as, overlapping,  
or adjacent to said transcriptional regulatory protein DNA response element for binding to  
a DNA binding compound;

(iii) a transgene and the coding sequence for a transcriptional regulatory protein  
under the control of and operably linked to said regulatable promoter; and  
the DNA binding compound,

wherein the DNA response element binds a transcriptional regulatory protein  
which comprises a repressor selected from the group consisting of Kruppel (KRAB), kox-  
1, TetR, even-skipped, LacR, engrailed, hairy (hes), Groucho(TLE), RING1, SSB16,  
SSB24, Tup1, Nab1, AREB, E4BP4, HoxA7, EBNA3, Mad and v-erbA.